RULE 132 AFFIDAVIT

In the United States Patent and Trademark Office

Applicant: Thomas Blaszczykiewsicz
Serial No.: 09/503,429
Filed February 14, 2000
For: BREATHABLE NEOPRENE SUBSTITUTE

Examiner: Alexis A. Wachtel
Art Group: 1771

DECLARATION UNDER 37 C.F.R. § 1.132

I, Tamer Elsamahy, declare and say:

That I was graduated from State University of New York at Buffalo in 2000 with a Bachelor of Science in Mechanical Engineering and completed all degree requirements leading to a Master of Science degree in Mechanical Engineering in July 2003;

That I have worked in the field of laminated foam products since August 2002;

That I am familiar with the above-identified patent application and with the references cited by the Examiner, i.e. U.S. Patent No. 5,139,476 to Peters, the Peters patent, and U.S. Patent No. 5,900,087 to Chakrabarti, the Chakrabarti patent;

That the following tests were performed by me to compare various characteristics of the material disclosed in the Peters patent with the polyurethane-spandex laminate disclosed and claimed in the above-identified patent application;

Lamination Strength Test

Material and Method

The claimed polyurethane – spandex laminate (BOP) and the Peters composite (flame laminated) which consists of a Spandex → Foam → Spandex laminate were tested for lamination strength. The open cell foam layer is the hub between the two knit fabrics. A Mitutoyo gauge with a 25 mm anvil was used to measure the thickness of both laminates. The measured thickness for both composites was ~ 6 mm.

Peel testing was performed on 0.75"x 9" test strips. The peel test is one measure of durability. The average of three strips per material was tested and tabulated in Table 1 below. The claimed material displayed the highest strength. Refer to Doc. # R001-628 in Appendix A for a detailed description for testing bond strength.

Results

. **Table 1.** Bond Strength Values.

Material	Bond Strength (N)
BOP	19.25
Peters	4.10

N = Newtons

As can be seen in Table 1, the bond strength of the claimed BOP material is over 4 times greater than the bond strength of the material cited in the Peters patent.

Stretch and Recovery Test

Material and Method

Sample specimens (3" x 0.75" x 0.25") for both Peters material and BOP were mounted in a tensile machine. (See Figure 1). The initial length of the sample is set at 1 inch. The material was then elongated in 1 in. increments, where load was recorded and returned to zero tension. At the end of each cycle, the relaxed length or rebound value is recorded (at a point of no load). The cycle was repeated until failure occurs. The stretch and recovery test is described in greater detail below. Graph 1 illustrates the performance of the two samples tested.

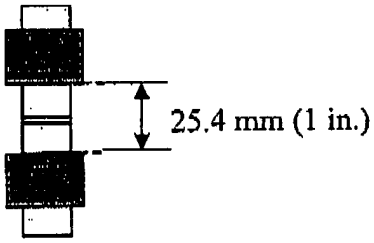
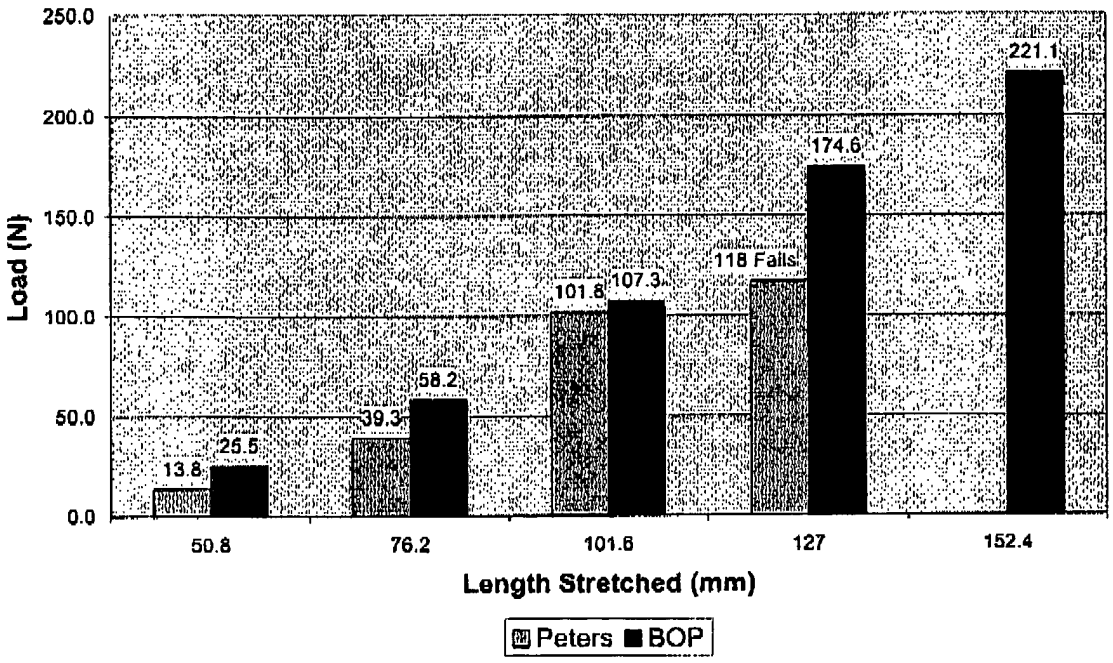


Figure 1



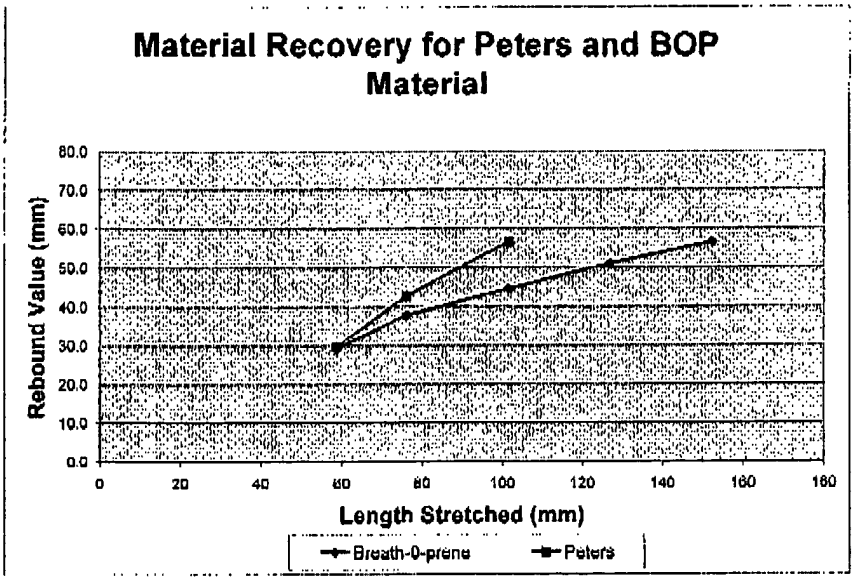
Graph 1

Results

The point of rupture of the Peters material occurred at 118 N at a recorded length of 114 mm (4.5 in.), whereas the BOP did not rupture before the machine head reached its maximum height. The value of 221 N was the final load recorded at a stretch distance of 152 mm (6in.). The breaking force is known to surpass 221 N. The results show the BOP to be higher in tensile strength than the Peters, deeming the material to be more durable.

Rebound value is the length of the sample after a return to a relaxed state. The Peters material exhibited the highest rebound value. It also demonstrates the Peters material to be low in its Yield Strength. The Yield Strength is a point in a material which goes from elastic deformation to plastic deformation. Elastic deformation is temporary deformation, in which a material fully recovers when a load is removed. Plastic deformation is permanent deformation; a material does not fully recover after a load is removed, although a small elastic component is recovered.

Graph 2 illustrates material recovery in both materials after being incrementally stretched at 25.4 mm (1 in). Due to the Peters material being low in tensile strength, three points were only recorded. Comparing point-point on both materials, the BOP recovered 22% more than the Peters material.



Graph 2

Porosity Test

Materials and Methods

A 5" diameter swatch of material to be tested is placed in an Accustron testing machine. Regulated air is passed thru the material at a specified rate. Sensors on the adjacent side measure the amount of air passing through the material (see Figure 2 below). Results of breath ability for the two materials were obtained:

Peters: 250 L/m^2/s

BOP: 36 L/m^2/s

To obtain the CFM of the above values, divide by 6 (A 6:1 relationship).

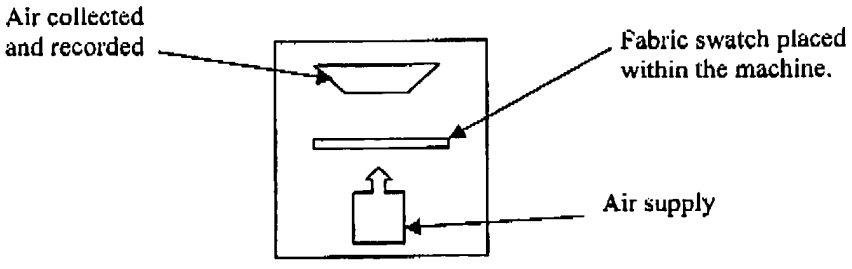


Figure 2

Results

The results of the porosity test were as follows:

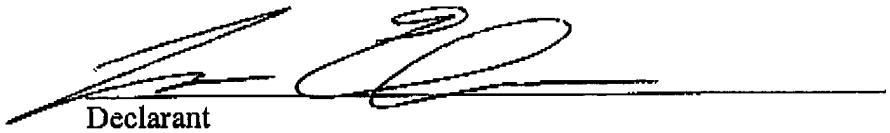
Peters Material: 250 m^2/sec
Breath – O – Prene: 36 m^2/sec

The results of the porosity demonstrate a significant difference between the porosity of the subject material claimed in United States Patent Application No. 09/503,429 in that the porosity, or breathability, of the Peters material is 6.94 times greater than that of the material claimed in the '429 application.

That the above described tests demonstrate the patentable differences between the material claimed in United States Patent Application No. 09/503,429 and the material disclosed in the cited Peters patent.

That the under signed declares further that all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statement sand the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon;

Further declarant saith not:



Declarant

10/6/03

Date

APPENDIX A

5

Rev	Change Note	Date	Create/Revised by		Checked by	
			Name	Initial & Date	Name	Initial & Date
1	C9169	16th June 03	ND Berridge		Gary Robinson	

T-Peel Test Method – Headgear Laminates

1. PURPOSE

The purpose of this document is to define the agreed test method and acceptance limits to be used by all parties in performing T-Peel acceptance tests for headgear laminates used in ResMed headgears.

2. SCOPE

This document is intended to be generic – it is not specific to any particular test machine, nor does it endeavour to give detailed "operator level" instructions. In most cases it is anticipated that a local instruction will be needed to supplement this document method, with detail instructions on driving a particular machine, managing the data, and analysing and reporting the data.

This document covers the material that is laminated into sheets and manufactured into the finished headgear product that is used in ResMeds reusable mask systems.

It is intended that the test be suitable to be used at various stages in the process of manufacture, or post-manufacture.

3. DESCRIPTION OF PRODUCT UNDER TEST

The product being tested is a laminated fabric, comprising a central open cell foam layer, sandwiched between two fabrics. A flame lamination process is used to bond the 3 components together. The test determines the force required to pull the layers apart.

4. TESTING & SAMPLING REQUIREMENT BY HEADGEAR MANUFACTURER

Traceability of input rolls is to be retained, such that it is clear when testing which foam, lycra and UBL rolls and lots correspond to which position on master roll from laminator.

There are three stages when the testing is to be carried out:

- Upon delivery of laminated material from supplier
- Strip test after cutting roll to size
- Final product testing

It is recommended that the supplier of the laminated material perform material testing per 4.1, prior to delivery of material to headgear manufacturer.

4.1 Testing of laminated material.

Upon receipt of laminated roll, three test strips are cut from one end of the roll and tested per test procedure below. If these meet the average mean force but fail the lower 3 sigma value then take a further three test strips from the opposite end of the roll and test per procedure. Both sets of results are then used to determine the mean and lower values. If these meet specification then the whole roll is accepted, if not then the whole roll is rejected.

4.2 Strip testing

Roll is cut into sheets approximately 3-4 yards long. These are then piled between 8 and 10 layers high. The headgear is then cut out of the sheets as well as three test strips from sheets 2, 5 and the top sheet. The 9 test strips are then tested per procedure below.

4.3 Final product testing

The final headgear is packaged in cartons that hold either 200 or 300 finished products. 5 samples from the 200 or 7 samples from the 300 are tested per procedure below.

NB If any group of samples fail the required specification then ALL the headgear that is made from that particular roll are rejected. At this stage the roll and all its test samples should be put aside for further analysis.

4.4 Tab testing

As with final product testing 5 samples from the 200 carton or 7 samples from the 300 carton are tab tested

4.5 Recording of test data

Results from above four tests are to be noted on Certificate of Conformance (Appendix A).

A Certificate of Conformance must accompany each shipment.

5. TEST PROCEDURE

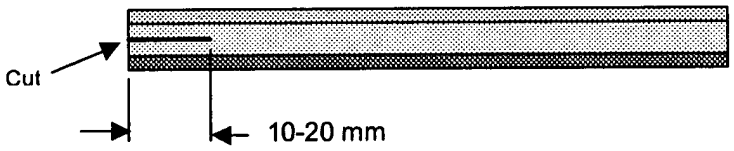
Sample width: 19mm.

Sample length: Minimum 150mm

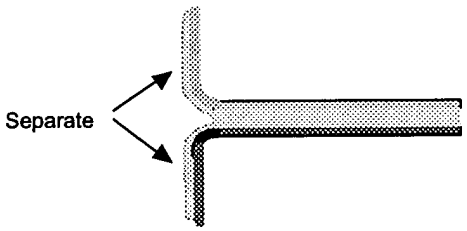
Orientation: Lycra lines down length of sample

Sample Preparation: Sample sides to have no burrs or tears. When cutting from sheet, an appropriate cutting die shall be used. .

- With a sharp blade make a 10-20 mm deep incision in the centre of the foam layer



- Using your fingers pull apart both fabrics sufficient to allow the sample to be clamped in the jaws, and to allow manipulation so the sample is well aligned without excess slack. The required distance will vary according to the clamps. An indicative distance is 30mm on each side.



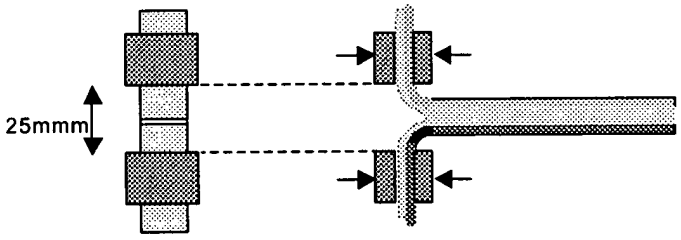
Test configuration: T peel

Jaw Separation at start of test: 25mm

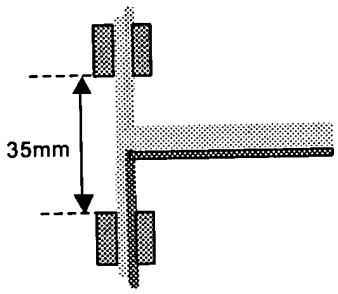
Jaw clamp method: Parallel push, with sufficient access to allow sample to be aligned, straightened, and excess slack removed.

Clamp coverage: All width of sample shall be within clamp

Sample alignment: Nominally aligned to the eye in all planes along test axis, i.e. 90 degrees in all planes.



Maximum slack: Slack in sample shall have been removed within 10mm of crosshead travel



5.1 Equipment specification

Typical test Load 26N. Cell shall be chosen accordingly.

Crosshead speed: 50mm/min

Crosshead travel distance: 100mm

Test Path displacement range: From 70mm to 100mm

: The test is to be conducted on a tensile tester Test Equipment option 1 Electronic tensiometer (eg Instron, Zwick)

Test Equipment Option 2: The test may be performed using a load gauge mounted on a motor driven stand capable of moving the gauge at constant set speed. In this case, an output from the load gauge (analogue or digital) shall be used to provide a means to record against time. This may be done using a PC and a suitable interface such as RS232, or via a chart recorder and paper. Care shall be taken in calibration of speed against time to obtain displacement, and ensuring that load recorded on the computer or chart matches load shown on the gauge. Once a chart of load against displacement has been produced, the analysis may be commenced.

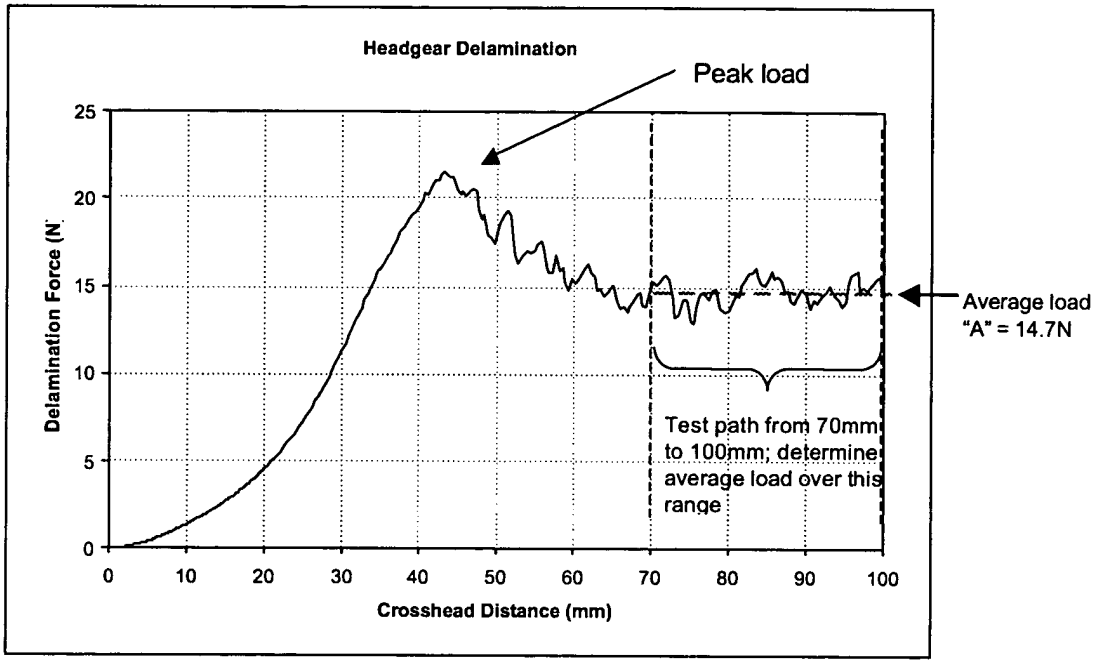
During test: Observe the tear surfaces. Record the interface and appearance of the fabric surfaces in the test path displacement region. Eg Foam/Foam tear, Lycra/foam separation with 10% residual foam.

6. METHODODLOGY

Load increases until foam tear is initiated. Since the cut has been made in the foam layer only, the initial peak load is accordingly a foam tear load. This load is not of interest. Where bond strength is low, the tear then propagates to the interface between foam and material and continues along this interface at a lower load than seen in the initial foam tear. Where bond strength is high, the tear remains in the foam. It is the average load seen towards the end of the test that is of interest, as this load distinguishes the well-bonded samples from the weakly bonded samples.

7. RESULTS CALCULATION

An example graph of displacement against load is shown below



For each sample tested, calculate the average force recorded over the displacement range from 70mm to 100mm. Record the average load "A" in Newtons to 1 significant figure.

Note 1: Where computer calculation is not available, the average over the defined displacement range may be determined graphically "by eye".

Note 2: The pull may be extended to ensure a 30mm displacement region for averaging is available after the peak has been passed. The displacement range was chosen so as to be sufficiently far into the peel to be past any initial peak, provided the sample slack and alignment requirements noted earlier have been observed. The graph should be viewed to confirm the region averaged is past the initial load peak. If the load peak was included, the value shall be disregarded, and the test repeated on a closely adjacent sample.

For each testing stage, laminated material test, strip test and final product test, determine the mean load "B" and standard deviation σ of the average loads "A".

Mean load "B" = sum of average loads "A" / number of "A" values

Record the value B in Newtons to 1 significant figure, and record σ in Newtons to 2 significant figures. Calculate:

Lower 3σ limit = mean load "B"- $(3 \times \sigma)$

Refer t headgear specifications f r delamination criteria.

For tab testing refer to relevant headgear specification

8. APPENDIX A,

Microsoft Excel
Worksheet